A RAND NOTE

SAMPLE SELECTION FOR THE PRESCRIPTION DRUG INFORMATION STUDY

Sandra H. Berry, David E. Kanouse,
William H. Rogers, with the assistance of
Jeffrey B. Garfinkle

August 1981

N-1657-FDA

Prepared For

The Food and Drug Administration

Rand
SANTA MONICA, CA. 90406

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PREFACE

The Prescription Drug Information Study was designed to determine how variations in informational leaflets (Patient Package Inserts or PPIs) given out with prescription drugs affect patients' knowledge, attitudes, and behavior. The study examines the effects of PPIs and seeks to pinpoint which design variables enhance communication and retention of important facts. These variables can then be emphasized in drafting regulatory guidelines for the design of PPIs. The study was conducted by The Rand Corporation under Contract 223-78-3009 with the Food and Drug Administration, Department of Health and Human Services. The data collection took place from October 1979 through May 1980.

This Note summarizes the objectives, procedures, and outcomes of sample selection for the Prescription Drug Information Study. It describes how pharmacies were selected for participation in the study and how customers were recruited from those pharmacies. It reports on the characteristics of the resulting samples of pharmacies and customers and assesses how well they meet the study's sampling goals. The data supply important evidence concerning the validity of the study's main findings. The Note should be of interest to those using data collected in the Prescription Drug Information Study and to researchers concerned with designing similar kinds of research.

Other Rand publications based on this project are:

Kanouse, David E., Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, Design of the Prescription Drug Information Study, N-1552-FDA, August 1981.

Kanouse, David E., Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, John D. Winkler, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Estrogen Leaflets, R-2797-FDA, August 1981.

Winkler, John D., David E. Kanouse, Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Erythromycin Leaflets, R-2798-FDA, August 1981.

Berry, Sandra H., David E. Kanouse, Barbara Hayes-Roth, William H. Rogers, and John D. Winkler, with the assistance of Jeffrey B. Garfinkle, Informing Patients About Drugs: Analysis of Alternative Designs for Flurazepam Leaflets, R-2799-FDA, August 1981.

Kanouse, David E., Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, and John D. Winkler, Informing Patients About Drugs: Summary Report on Alternative Designs for Prescription Drug Leaflets, R-2800-FDA, August 1981.

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Many Rand colleagues assisted in sample selection and field operations. Patricia A. Ebener, Susan J. Reese, Abby E. Robyn, and Ann M. Westine prepared data for the sample selection model. Janet Hanley assisted in preparation of computer files and performing sample selection runs. Laura A. Borden and Sandra D. Turner assisted in planning for contacting pharmacies. Liaison with pharmacies was coordinated by Susan L. Ritter and carried out by Patricia A. Ebener, Nancy de Varrennes, Susan J. Reese, Nomi H. Roth, Patricia E. Scheaffer, and Anne Marie Segal. Telephone interviewing was supervised by Laural A. Hill and Mary E. Morris and carried out by a persistent and talented group of interviewers. Linda M. Buhl coordinated the mail survey and data entry operations. Other colleagues, too numerous to name, assisted in all phases of these tasks. Carl N. Morris provided a helpful review of a draft of this Note. Evelyn W. Gordon, Nina Mocniac, Steve Moore, and Louis A. Morris, all of the Food and Drug Administration, provided useful comments. Diane Alexander, Sue Payne, Diane Reingold, and Lucy Wilson skillfully prepared the typescript, and Helen B. Turin provided able editorial assistance.

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I. INTRODUCTION AND SUMMARY

This Note describes how we selected samples of pharmacies and customers within pharmacies for participation in the Prescription Drug Information Study. It reports on the characteristics of the resulting samples and assesses how well they meet the study's sampling goals. It also describes randomization procedures for the experiment and evaluates the success of the data collection.

Printed information documents, known as Patient Package Inserts (PPIs), have been proposed as a way of informing users about the actions, indications, and proper use of prescription drugs. The Prescription Drug Information Study was a field experiment designed to test the effects of alternative design features of PPIs in enhancing communication and retention of important facts. The study was conducted in a sample of pharmacies with users of any one of three prescription drugs as subjects.[1] PPIs incorporating various design features were provided to drug users according to a predetermined random assignment schedule. The main elements of the study design are described briefly in Section II.[2]

The study involved 69 pharmacies located in Los Angeles County. These pharmacies enlisted the cooperation of 1820 of their customers who filled prescriptions for one of the study drugs during a period from October 1979 through May 1980. One PPI variant was given along with the

[1] The drugs were conjugated estrogens, erythromycin, and flurazepam (Dalmane). These drugs and the reasons for selecting them are described in Section II.

[2] The study design is described in detail in Kanouse et al. (1981a).

prescription to each customer who agreed to participate (except in the control group). We later interviewed each customer by telephone and sent a self-administered questionnaire to be completed and returned by mail. Each customer was paid $2.50 for participating.

The Food and Drug Administration (FDA) has proposed regulations that would require PPIs to be distributed by pharmacies when the prescription is filled. The pharmacy is the most natural setting in which to study the effects of providing PPIs. However, the selection of pharmacies then becomes an important aspect of study design. Moreover, in the present study, the pharmacies played two other crucial roles: They were charged with recruiting subjects for the study and with carrying out random assignment of the experimental PPIs.

The pharmacies were selected to provide customers from a wide range of ethnic, socioeconomic, and educational backgrounds and from a variety of treatment settings. Strict representation of the population was not a goal of the pharmacy selection. Because the study has an experimental design, the goal was to enhance internal validity by selecting pharmacies so as to increase the probability of observing any effects on dependent variables associated with the type of pharmacy or the characteristics of the customers. The data used to classify the pharmacies were drawn primarily from the 1970 Census of Population for Los Angeles County. To select pharmacies, we used a computer algorithm called the Finite Selection Model (FSM), which employed sample selection criteria in a way that maximized the statistical information from the sample. Naturally, the success of the sampling plan depends on the appropriateness of the criterion data used for selection and the extent

to which the final sample faithfully reflects the original sampling goals, after nonresponse and attrition are accounted for. These procedures are described and analyzed in Section III.

For ethical and practical reasons, the pharmacists selected potential participants. Although Rand managed the data collection, it was not possible for Rand staff to select participants from pharmacy customer lists or records in a systematic way, because the pharmacists could not reveal names of customers to an outsider without the customers' permission. The pharmacists therefore had to explain the study to each eligible customer and obtain the customer's authorization before they could give any information to Rand. As partial compensation for their efforts, we paid pharmacists $5.00 for each complete case. Although it would have been desirable for the pharmacist to approach every eligible customer, that was not possible. Sometimes the pharmacists were too busy, sometimes they did not ask customers who they felt would not cooperate, or would be unsuitable, or might be offended by being asked. This introduced an unsystematic element into selection of the sample, as discussed in Section IV.

The pharmacists were also responsible for carrying out the random assignment of customers to experimental conditions by providing participants with the correct PPI according to a predetermined schedule. Field studies with experimental designs have had major difficulties associated with circumstances that applied in this study--namely, that the randomization was carried out (1) by many people, (2) by non-experimenters, and (3) in locations remote from the experimenters (Conner, 1977; Rezmovic, Cook, and Dobson, 1981). We were especially

concerned about this problem, and our findings on this point are discussed in detail in Section V.

Finally, customers who agreed to participate in the study had to be contacted and interviewed by telephone. Those who completed the telephone interview were sent an additional questionnaire to fill in and return by mail. To ensure that interviews were properly conducted, we recontacted a subsample of the respondents for validation. This procedure and its results are described in Section VI.

The goal of the sample selection procedures was to produce a sample with sufficient variation in pharmacies and in customers chosen from those pharmacies to permit detection of any important effects associated with these variations in the resulting data. The checks we performed on how these procedures were carried out revealed no serious biases in the selection processes for pharmacies or for customers. Further, although the accuracy of the randomization was far from perfect (for example, 22 percent of the assignments were made out of order), we were not able to detect any biases introduced by the errors in assignment. Finally, the data collection procedures yielded acceptable response rates for the main collection instruments: an overall telephone survey completion rate of 87 percent and a mail survey completion rate of 82 percent across the three drugs. Based on our assessment of the sampling plan and procedures, we conclude that the analytic findings of the study are valid for the population from which the sample was selected and also apply to a diverse, though not necessarily representative, population of drug users.

II. DESCRIPTION OF THE PRESCRIPTION DRUG INFORMATION STUDY

This section provides a very brief description of the Prescription Drug Information Study. Readers who require more detail should consult Kanouse et al. (1981a) for a complete description of the design of the study.

BACKGROUND

In 1980 FDA promulgated regulations requiring drug manufacturers to provide, and pharmacists to dispense, informational leaflets (PPIs) to patients filling prescriptions for a wide variety of drugs.[1] Initially, the regulations would apply to ten classes of prescription drugs,[2] with the possibility of later extensions, revisions, modifications, or curtailment based on the results of the early program. After the final regulations were issued, the new administration stayed their effective date, consistent with President Reagan's executive order.[3] At this writing, the FDA Commissioner is conducting a full review of the patient prescription drug labeling program, to determine whether the benefits of PPIs outweigh their costs and to assess the relative advantages of alternative means for delivering drug information to patients.

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[1] Food and Drug Administration (1980)

[2] The ten drugs and classes of drugs are: ampicillin, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, phentoin, propoxyphene, thiazides, and bendectin.

[3] Executive Order No. 12291, "Federal Regulation," February 17, 1981.

The research on which this Note is based is the most thorough investigation conducted thus far on the effects of PPIs. It represents a prospective study of the effects of various prototype PPIs on actual drug users. The major purpose is to determine how specific features of PPIs affect patients' knowledge of the drug's purpose, actions, contraindications, and side effects. Other outcomes of interest include self-reported compliance with drug regimens and reporting of side effects.

PRESCRIPTION DRUGS SELECTED FOR THE STUDY

Three commonly used drugs were selected for this study. These drugs have different usage patterns and present different problems in providing information to patients.

- o Erythromycin is an antibiotic usually prescribed on a short-term basis. Improving short-term compliance is a major purpose of providing a PPI for this drug.
- o Flurazepam hydrochloride, or Dalmane, is a hypnotic drug used to treat sleep disturbances. It is a member of a class of drugs that includes Valium and Librium. Providing instructions for proper use and avoiding interactions with other drugs and alcohol are major purposes of the PPI.
- o Conjugated estrogens are hormones frequently used to treat vasomotor symptoms of the menopause. A major purpose of the PPI for this drug is to inform the patient about serious dangers associated with long-term use of the drug. A PPI has been required for this form of estrogen since 1977.

The patients who take these drugs differ in their personal characteristics. Erythromycin is used by both sexes and all age groups, including children. Dalmane and estrogens are used almost exclusively by adults. Dalmane is taken by both men and women, estrogens primarily by women.

STRUCTURAL VARIATIONS OF PPIS AND STUDY DESIGN

Two criteria apply to the variables chosen for testing in the PPI leaflets. They show promise of enhancing the patients' retention of important facts; and they are, in principle, subject to FDA's regulatory control.

Study 1

- Specificity of instructions--the extent to which readers are provided with behaviorally oriented instructions on how and when to take the drug, what to do about adverse reactions, etc.
- Amount of explanation--the extent to which core facts about the drug are elaborated with explanations about why it works as it does, why certain people should not take it, why certain side effects may occur, etc.

Study 2

- Risk emphasis--the extent to which the PPI uses structural and formatting devices to highlight information about risks, precautions, dangers, and side effects, rather than simply

presenting the same information without special emphasis.

- o Writing style--the extent to which the language is simplified to facilitate comprehension; simplified versions use fewer technical words, contain shorter sentences, use the active voice more frequently, and follow other rules designed to minimize reading difficulty.

Study 3

- o Format--text versus outline: The text version presents information in full sentences and paragraphs; outline versions present key words and phrases organized under major headings.
- o Length--full content versus reduced content: The full content version contains all "core" facts about the drug; the reduced content version covers fewer facts (e.g., does not list as many side effects).

These variables were tested in three studies, each of which used a 3x2x2 factorial design with three levels of drug (a nonrandom factor), and two of the six structural variables, each with two levels. The factorial combination of variables changed from study to study. Study 1 tested specificity of instructions and amount of explanation; Study 2 combined risk emphasis and writing style; and Study 3 examined format and length. For example, in Study 1 there were four PPI variations: core facts with no explanation or specific instructions, core facts with explanation, core facts with specific instructions, and core facts with

explanation and specific instructions.[4] In each study there was also a control group of subjects who did not receive any of the experimental leaflets. The control group for estrogen received the manufacturers' leaflets, as required by FDA regulation. Control groups for erythromycin and Dalmane received no leaflets.

The three studies were conducted sequentially for each drug in each pharmacy that participated. Procedures for selecting customers within pharmacies, carrying out the randomization, and collecting survey data from customers were the same for all of the studies. These procedures are described in Sections III through VI.

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[4] Analyses and results for leaflet variations for estrogens are reported in Kanouse et al. (1981b); results for erythromycin are reported in Winkler et al. (1981); and results for Dalmane are contained in Berry et al. (1981). A summary of the results is contained in Kanouse et al. (1981c).

III. SELECTING THE SAMPLE OF PHARMACIES

We designed the pharmacy selection procedure with three goals in mind: first, that the sample of experimental subjects represent a wide range of ethnic, socioeconomic, and educational backgrounds; second, that subjects be drawn from a variety of pharmacy settings; and third, to minimize travel costs as much as possible, within the constraints imposed by the first two goals. To balance these criteria and choose the actual pharmacies, we used a computer algorithm called the Finite Selection Model (FSM). This algorithm selected pharmacies in a way that enhanced the probability of observing any effects associated with the characteristics of the pharmacy customers or the pharmacies themselves.

Figure 1 provides an overview of how the actual sample of pharmacies was selected. First, we used U.S. Census maps of the county, U.S. Census data, and telephone directory listings to compile data on each pharmacy in Los Angeles County. These data formed the basis for selection of an initial sample of pharmacies using the FSM. Next, we approached this initial group of pharmacies to seek their cooperation in the study. Pharmacies that accepted and produced usable cases became part of the final pharmacy sample. Pharmacies that were too far away, that did not dispense retail prescriptions, that refused, or that failed to produce cases were replaced by pharmacies with similar customer and pharmacy characteristics. Finally, pharmacies that produced some cases, but not a sufficient number to meet our sampling goals, were supplemented with additional pharmacies having similar characteristics.

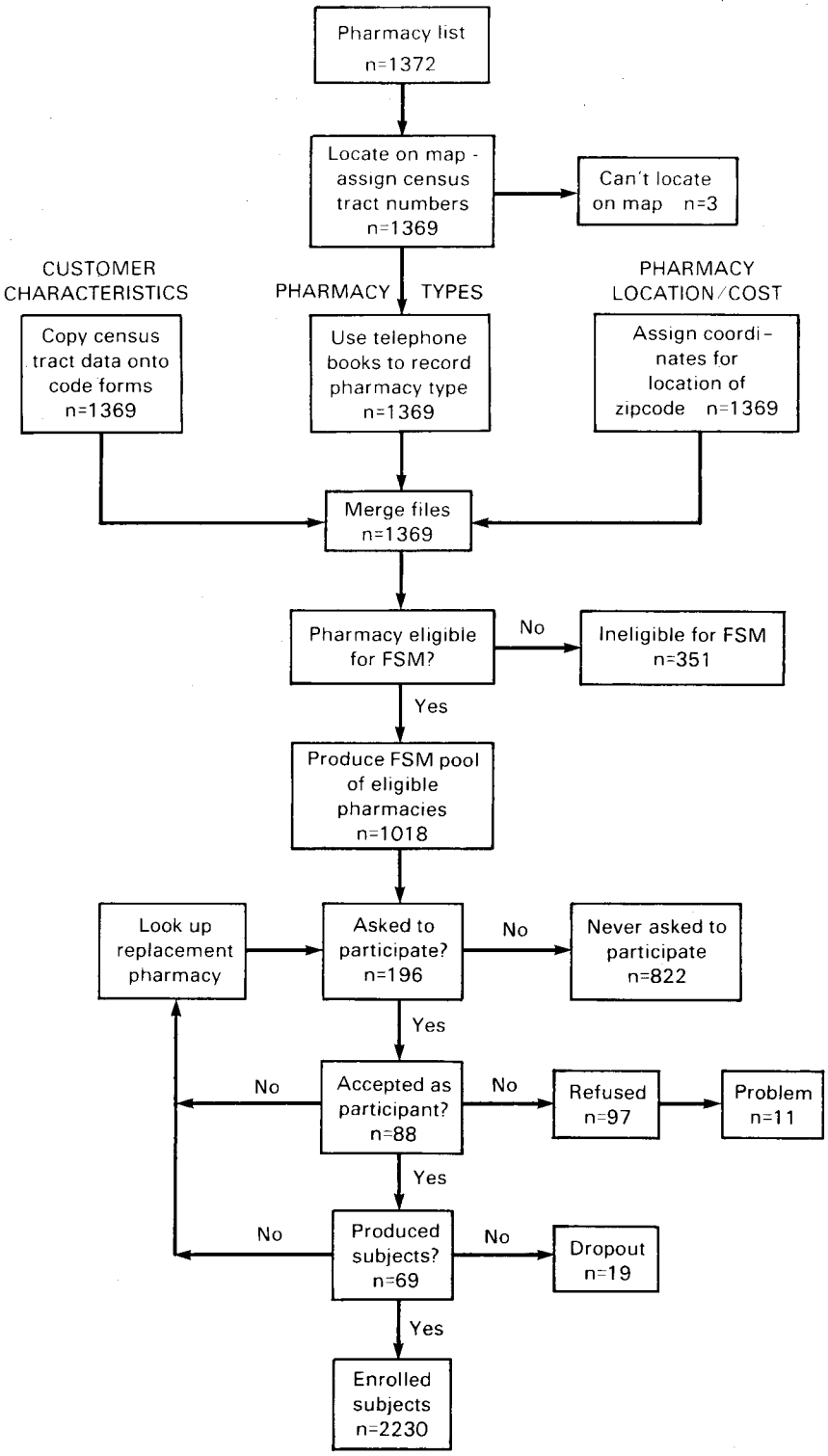

Fig. 1 — Steps in the pharmacy selection process

DESCRIPTION OF THE FINITE SELECTION MODEL

The Finite Selection Model provides an effective way to choose a sample and is especially well suited to studies with experimental designs (Morris, 1979). It selects samples that are statistically powerful yet representative of the sampling frame.

The FSM was our preferred solution to the sampling problem we faced, but we did consider other alternatives, including some classical methods that are easier to justify.

- Simple random sampling is easy to do and can be rigorously analyzed with analysis of variance procedures, although the existence of distant (and prohibitively costly) pharmacies makes the sampling frame complex. Further, if pharmacy customer and pharmacy characteristics are confounded (for example, if all low income customers are from institutional pharmacies) it may be difficult or impossible to detect interactions between PPI types and pharmacy or customer characteristics.
- Stratified random sampling is very close to the model we actually used. If the pharmacy and area characteristics are discrete, the two methods are equivalent. The FSM generalizes stratified sampling by allowing more variables and continuous variables. This last feature is important because four of the five criteria used in the FSM sample selection were continuous variables. If, instead, these were grouped into three categories each, the result would have been $3^5 = 243$ strata, many of which would have been empty.

- The use of cluster analysis to create the strata eliminates empty strata but introduces other complications. Cluster centers may be unbalanced in the explanatory variables, leading to insufficiently diverse choices. We rejected this method partly because of the high cost of clustering the numerous points in our sample frame.

We also rejected other procedures that dealt more crudely with the need to consider cost in selecting the sample. For example, it might have been possible to lower the data collection costs by choosing a smaller number of pharmacies and obtaining more subjects from each one within the prescribed time period for the study. Such a strategy would have required us to assume a degree of cooperation from the pharmacies that we felt was unrealistic, based on the results of a pretest of data collection procedures. We could also have chosen a random sample with unequal probabilities determined by cost. However, such a strategy does not guarantee sample diversity, and the potential advantage of simplicity in weighting the observations for analysis is lost if some pharmacies refuse to cooperate. Finally, we could simply have chosen the most conveniently located pharmacies without regard to their characteristics, which might well have made the sample grossly unrepresentative.

The FSM is an extension of stratified random sampling, although one that is intended to provide optimal designs for linear regression. The investigator specifies the criteria to be optimized and rates the effects (treatment or covariate) by the precision required in estimating their regression coefficients. Randomness and representativeness are

introduced by making the treatments "choose" sample units in a randomized order. This works like a sandlot baseball game in which teams choose players in balanced, random order in each round. Each team (treatment) wants the best players (the most informative sample points) and also players that fit together as a team (combinations of informative sample points). The teams end up evenly matched and have an appropriate number of players at each position. This contrasts with a simple random sample where it is possible for all the pitchers and all the catchers to end up on the same team. Continuous variables are included without the need for arbitrary division into categories. The statistical efficiency of the FSM compared with random sampling is calculated in the FSM program. In this case, the sample initially chosen by the FSM was 14.4 percent more efficient; that is, the FSM sample of 41 pharmacies yielded the efficiency of 47 randomly sampled pharmacies--but the resulting sample was still a probability sample.

SAMPLING FRAME

The sampling frame for the study consisted of a list, provided by the California State Department of Consumer Affairs, of 1372 licensed pharmacies in Los Angeles County as of March 1979. Because Los Angeles County covers an area of 4069 square miles and parts of it lie as many as 45 miles from the study headquarters (not to mention 26 miles across the sea), we might have spent considerable resources attempting to cover the entire county. We visited each pharmacy weekly, so that cost of travel was a serious consideration in selecting pharmacies for the study. But we did not eliminate any pharmacies from the sampling frame

simply on the basis of cost. It was considered as one factor in using the results of the FSM. Other factors being equal, we selected the lowest cost pharmacy.

SELECTION OF STRATIFICATION VARIABLES

The sample characteristics that might be expected to affect response to the experimental PPIs were used in the FSM as criteria for selecting the sample. These were characteristics of the pharmacy customers and of the pharmacies themselves. Customer characteristics were estimated from the average educational, income, race, and ethnic characteristics of the surrounding neighborhood. These demographic characteristics were expected to be systematically related to customers' knowledge, attitudes, and behavior, independent of the experimental manipulations. In addition, we believed such characteristics might interact with one or more of the experimental treatments. Finally, the sample design we used facilitates generalization to populations with different, but specified, demographic characteristics.

In addition to these demographic characteristics, the FSM used one major pharmacy characteristic--whether the pharmacy was managed independently or as a chain. This variable was chosen because of the importance of estimating the effects of providing drug information across a variety of pharmacy settings.

PREPARING DATA FOR SAMPLE SELECTION

Application of the FSM requires that the data on each potential sample element be available in machine readable form. Accordingly, for

each of the 1372 pharmacies in the sample frame, we constructed a vector of characteristics describing the individual pharmacy and its customer population and entered the information in the computer. Because we had no direct information on the characteristics of actual pharmacy customers, we estimated these characteristics from the characteristics of residents in the surrounding area. Such a procedure is reasonable if one assumes that most of a pharmacy's customers tend to live nearby or are similar to those who do. We used 1970 U.S. Census data to determine average neighborhood characteristics along the dimensions of education, income, race, and ethnicity. We then classified each pharmacy as an independent or part of a chain by examining alphabetical lists of pharmacies and yellow pages entries in county telephone books.

The data we received from the California State Department of Consumer Affairs included only the state license number and the name and address of the pharmacy, including the zip code. This information was entered on a computer file so that it could be combined with other data generated for the FSM.

Estimation of the characteristics of pharmacy customers required two steps. The first was to abstract the required items from the published volumes of the U.S. Census of Population for each census tract in Los Angeles County.[1] The second step was to associate each pharmacy with the appropriate Census tract data. We located each

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[1] We used four pieces of data: median years of school completed (by adults), median income (of all families), percent Negro, and percent Spanish. The first three were simply copied; percent Spanish was calculated as the total of persons of Spanish language and other persons of Spanish surname divided by the total population of the tract. This information was manually coded, then entered on a computer file.

pharmacy address on a Census tract map of the county. Because any pharmacy could be located on the border of two tracts, simply recording the number for the tract in which it was located would not always be a good description of the surrounding area. Instead we constructed a template that outlined a circle one mile in diameter and placed it over the exact location of each pharmacy. We then recorded the number of each tract that was wholly or partly contained within the circle and the approximate percentage of the circle each tract covered. The result, for each pharmacy, was a list of nearby tracts and a corresponding set of weights (percentages) that summed to 100. Using these data, and the Census tract data described above, we created a "synthetic" Census tract for each pharmacy by calculating a weighted average of the characteristics of all nearby tracts, where the weights were proportional to the percentage of the surrounding area covered by each tract. This yielded a computer file with each pharmacy matched to a set of characteristics from the 1970 Census for people living within a one-half mile radius of the pharmacy.

We used two sources to code whether each pharmacy was operated as an independent or as part of a chain. The first was the master list of pharmacies, sorted alphabetically by pharmacy name. A pharmacy was coded as part of a chain if it met any of the following criteria: (1) it was part of a well-known chain; (2) the name of the pharmacy contained a store number (e.g., Valley Pharmacy #12); or (3) the same name appeared more than once on the listing. We verified classifications based on the third criterion before coding by consulting telephone directories. Directories were also used to identify other

chains in which more than one pharmacy location was listed in the same advertisement, even though the names were different. In some cases we called the pharmacy to verify its status. Pharmacies of unknown status, clinic pharmacies, and hospital pharmacies were assigned a neutral status with a numerical value midway between chain and independent.

We used zip codes to code pharmacy location, which was not included in the FSM but was an additional selection factor. We located each zip code on a zip code map of the county and recorded its coordinates from a clear plastic grid superimposed on the map. The coordinates located the zip code within a one and one-half square mile area and permitted us to compute a travel cost factor.

These procedures resulted in a file of 1369 pharmacies--the original 1372 less three that could not be located on any map (see Fig. 1). We then excluded certain pharmacies from the file, including nonretail (pharmacies whose patronage was limited to students, union members, etc.) and nonprescription (herbal or homeopathic) pharmacies. Finally, we eliminated pharmacies if the surrounding area was more than 20 percent Hispanic, because a significant portion of their customers would not be able to read the PPI leaflets, which were only provided in English.[2] After these exclusions, 1018 pharmacies remained.[3]

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[2] Although the use of a 20 percent criterion for excluding Hispanic neighborhoods may seem too conservative to some, we deliberately chose a conservative criterion to allow for the dramatic demographic changes known to have occurred in Los Angeles County during the 1970s. Many neighborhoods that were 20-25 percent Hispanic in 1970 were predominantly Hispanic by 1979.

[3] We deleted 351 of the 1369 pharmacies. Five were duplicates of other pharmacies, 329 were in areas that were 20 percent Spanish or more, the remaining 22 were nonretail or nonprescription.

APPLICATION OF THE FINITE SELECTION MODEL

Because chain pharmacies carry an additional management layer, we expected that it would be more difficult and time-consuming to enlist their cooperation in the study. All things being equal, we preferred to deal with fewer chains. We accomplished this by tying the selection of some pharmacies to that of others from the same chain. This use of the FSM produced probability samples of pharmacies with fewer different chains than one would expect from random selection.

The FSM produced 25 subsamples, with about 39 pharmacies in each subsample, and one larger left-over group. Then, we randomly selected one of the 25 subsamples; it contained 41 pharmacies. This initial list was the basis for selection of the first group of pharmacies we asked to participate in the study.

Based on a pretest, we believed that many of the pharmacies we asked to participate would refuse. Further, we knew that some pharmacies selected in the FSM would be too far away and that some of the pharmacies that agreed to work with us would drop out before the study was completed. To facilitate field operations, we devised a simple procedure to replace an uncooperative pharmacy with one having similar pharmacy and customer characteristics. For each of the 41 pharmacies selected by the FSM, we generated a list of 11 pharmacies most similar according to the same criteria used in the original selection. This list included a measure of cost. Similarity was measured by the sum of the standardized characteristic differences. Whenever a pharmacy was eliminated, we replaced it with a similar pharmacy from the list. Usually the replacement pharmacy was the most

similar one available; in some cases, however, it was the most similar one available at reasonable travel cost. This procedure allowed us to maintain continuous field operations because if a replacement was required it could be readily identified without additional computer runs. The procedure was also used to supplement or replace pharmacies that did not generate enough cases during the period of the study.[4]

Over the course of the study, we selected 196 pharmacies as potential participants. Of these, 88 (45 percent) accepted, 97 (49 percent) refused, and 11 (6 percent) were found to be demolished, relocated, or to have no walk-in business. Of the 88 that accepted, 69 (80 percent) provided at least one case. We received a total of 2230 cases from all the pharmacies, a mean of 32 cases per pharmacy. Of these, 1820 resulted in completed interviews, for a completion rate of 82 percent.

OBTAINING COOPERATION FROM THE PHARMACIES

Although pharmacies selected by the FSM could be "replaced" if necessary, it was highly desirable that each selected pharmacy be induced to cooperate. Replacements were never exact duplicates of the pharmacy that had been selected originally, and they were often more

[4] Each of the 41 pharmacies selected in the original sample represented a particular combination of characteristics. We desired a minimum of 28 cases from each representative pharmacy (the average expected caseload was 55 cases) spread over 175 days. To decide whether a pharmacy was likely to produce the minimum number of cases, we tested the hypothesis that k or fewer cases would be observed in n days. For the sake of simplicity, we treated this as a simple binomial problem and prepared a table with values of n specified for values of k. If the production of a particular pharmacy fell below k cases in n days, it was supplemented with a similar pharmacy.

expensive (farther away from study headquarters) than the one they replaced.

Before approaching pharmacies, we obtained letters endorsing the study from the American Pharmaceutical Association and the California Pharmaceutical Association. These were combined with samples of PPIs, information brochures, and other study forms into a folder for each pharmacy. When approaching a pharmacist for the first time, a staff member[5] took these materials as an aid in explaining the study. The materials were then left for the pharmacist to read at leisure. We did not press pharmacists to agree to participate on our first visit, because we judged that if pharmacists were familiar with what the study required before they agreed, they would stand a better chance of participating longer. In independent pharmacies, the pharmacist was usually the owner and was able to decide whether to participate on his own. In some larger pharmacies, or in chain pharmacies, we contacted the main office in addition to the pharmacy that had been selected.

Most pharmacists we approached were willing to listen to a description of the study and to accept the materials to read. Most were also familiar with the issue of providing PPIs and had strong feelings about it. Although many of the pharmacists who participated in the study were opposed to PPIs as a mandatory requirement, many others who opposed PPIs refused. Pharmacists' generally negative attitudes toward PPIs contributed substantially to the high refusal rate we experienced. Other reasons pharmacists gave for refusing were that they were too

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[5] Pharmacies were contacted by a member of the senior staff of the project accompanied by the staff member who would visit the pharmacy regularly once it had agreed to cooperate.

busy, that they did not wish to fill out any more forms, that their pharmacy was not arranged to permit easy access to customers by the pharmacists, and that the physicians whose patients the pharmacy served would object to the pharmacist's participation.

When a pharmacy agreed to participate, we immediately provided the pharmacist with the necessary materials and instructed him or her (and other staff members designated by the pharmacist) in how to enroll customers. Pharmacists varied in their success at obtaining the cooperation of their customers for the study. Failure to enroll any customers was the main reason for pharmacies dropping out of the study after initially agreeing to participate.[6]

As shown in Table 1, the pharmacies that participated in the study ranged from small independent pharmacies to large chain and institutional pharmacies.[7] Although we cannot completely rule out the possibility of bias introduced by the high pharmacy refusal and drop-out rate we experienced, the diversity among the pharmacies that did provide subjects ensures that we obtained results from a broad range of pharmacy types. The participant pharmacies operated in a variety of locations. They employed, on average, two full-time pharmacists and 2.5 other staff members. Information provided by customers who participated in the study about how they select a pharmacy[8] leads us to believe that the

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[6] We used a number of methods to keep pharmacies involved in the study, including "newsletters," invitations to study headquarters for tours, and personal visits to pharmacies by the senior staff of the project.

[7] Hospital in-patient pharmacies were not included in the study.

[8] Questions were asked in a mail survey completed by 1491 participants in the study who had previously been interviewed by telephone. The survey is described in Section VI.

Table 1

CHARACTERISTICS OF PHARMACIES THAT PROVIDED CUSTOMERS[a]

(Percent)

Characteristic	Pharmacies	Complete Telephone Interviews
Ownership type		
Independent	81.2	59.5
Chain	11.6	29.2
Franchise or agency	4.3	7.1
Institutional	1.4	1.9
Health Maintenance Organization	1.4	2.3
Total	100.0	100.0
Location		
Shopping center	39.1	47.6
Business street	33.3	28.5
Medical building	1.4	1.9
Outpatient clinic	26.1	21.9
Total	100.0	100.0
Number of prescriptions filled per day		
50 or less	19.1	15.4
51 - 75	20.6	13.3
76 - 100	23.5	22.7
101 - 150	19.1	25.8
151 or more	17.6	22.7
Total	100.0	100.0
(Total Cases)	(69)	(1820)

[a]Based on responses to a short questionnaire administered in person to 69 pharmacists who enrolled subjects for the study. Percentages may not sum to 100 because of rounding.

participating pharmacies were not "special." The most common reason customers gave for selecting a pharmacy was the convenience of its location. Liking and trusting the pharmacist was the second most common reason, and low drug prices the third.

ASSESSMENT OF PHARMACY SELECTION PROCEDURES

The available data permit us to assess the results of our pharmacy selection procedures in two ways. First, we can compare the actual sample of pharmacies with the population of eligible pharmacies to see how well the sampling plan was carried out and whether any sources of nonresponse bias can be observed. Second, we can compare the actual characteristics of participants we obtained from each study pharmacy with the characteristics that were predicted from the 1970 U.S. Census data for the area surrounding the pharmacy. This tests our assumption that a pharmacy's customers are similar to the people who live near the pharmacy.

Comparison of Pharmacy Sample with Pharmacy Population

The original group of 41 pharmacies selected by the FSM represented a statistically desirable mix of pharmacy and customer characteristics. As noted above, however, a majority of the pharmacies we approached refused to participate or did not produce the desired number of cases. Although we replaced each of these pharmacies with a similar pharmacy, the characteristics of the pool of customers from which the cases were recruited changed with each replacement. Although each replacement was as much like the original pharmacy as possible, the fact that each

pharmacy was selected for more than one characteristic meant that the replacement might be a close match for the characteristics as a whole, but it might be somewhat different for any single one. Further, the number of pharmacy replacements required to achieve the desired number of cases differed among the original group of 41. Thus, the characteristics of the pharmacies that produced the study subjects could be quite different from those of the sample of pharmacies originally selected by the FSM.

Table 2 compares the various categories of pharmacies for population, original sample, actual sample, weighted sample, and refusals. For each category the table provides the values for means and standard deviations of customer characteristics of the pharmacies as predicted from the 1970 Census data. Lines 1 and 2 compare the sample pool of 1018 pharmacies available for the FSM and the first sample of 41 pharmacies selected by the FSM. The values are quite similar; the main apparent difference, percent black, is not statistically significant. Line 3 provides the corresponding values for the 69 pharmacies that contributed at least one cooperating customer to the study. In Line 4, the mean Census values are weighted by the number of customers from each pharmacy that agreed to participate and completed the telephone interview. Line 5 shows the characteristics of the 116 pharmacies that refused to participate or that dropped out without enrolling customers. Comparison of the values in Line 4 with Lines 1 and 3 indicates that pharmacies in areas with high concentrations of blacks recruited somewhat fewer study participants than other pharmacies, although this difference is not statistically significant. For each of the other

Table 2

VALUES OF CRITERION VARIABLES FOR SAMPLES OF PHARMACIES AT VARIOUS STAGES OF SELECTION[a]

Pharmacy Sample	Number of Pharmacies	Percent Black	Percent Spanish	Median Years of Education	Median Income (All Families)	Log of Income
1. All pharmacies included in FSM	1018	9.80 (24.13)	9.28 (4.08)	12.55 (0.83)	12,194 (3,878)	9.36 (0.31)
2. First sample drawn from FSM	41	7.99 (19.67)	8.76 (3.60)	12.65 (0.68)	12,038 (2,508)	9.37 (0.23)
3. All pharmacies contributing at least one cooperating customer to the study	69	9.52 (22.75)	8.71 (3.69)	12.66 (0.79)	12,288 (2,737)	9.39 (0.24)
4. Sample (3), weighted by the number of customers for whom interviews were completed	69	5.75 (16.62)	8.95 (3.56)	12.60 (0.58)	12,300 (2,508)	9.39 (0.23)
5. Refused or dropped out	116	9.93 (23.90)	8.13 (3.51)	12.62 (0.60)	11,963 (2,258)	9.37 (0.19)

[a]Entries represent category means across pharmacies. Standard deviations are shown in parentheses.

characteristics, however, the differences between the unweighted and the weighted sample and between the weighted sample and the population are small and not statistically significant.

In general then, we conclude that except for a slight trend toward underrepresentation of blacks, the pharmacy sample actually obtained is reasonably representative of the population of eligible pharmacies, at least as measured by a set of important demographic characteristics. Further, the pharmacies that refused or dropped out were not significantly different from the ones that provided cases, reducing the possibility of nonresponse bias connected with customer characteristics.

Accuracy of Prediction of Customer Characteristics from Census Data

Another way of measuring the adequacy of the sampling procedures is to compare the values of criterion variables predicted from the 1970 U.S. Census with the actual values for pharmacy customers. Of course, there are several reasons to expect that the relationship between the two sets of criterion variables might be less than perfect. First, data on the characteristics of residents in the area surrounding the pharmacies comes from the 1970 Census and may be inaccurate nearly ten years later. Second, pharmacy customers may not be the same kinds of people as the residents in the surrounding area--for example, some pharmacies may be patronized mainly by people who work in the area or visit doctors in the area rather than by area residents. Third, the study is limited to customers taking one of only three drugs, and they may differ systematically from other pharmacy customers as well as from the general population. Despite these reservations, however, there was

good reason to expect that 1970 Census data would, on the whole, be quite useful in facilitating the selection of pharmacies from diverse neighborhoods. (Indeed, that is the reason we used them.) Fortunately, our data permit us to assess how useful they were.

To determine the accuracy with which Census data predicted the characteristics of pharmacy customers, we compared predicted and actual values for percent black, percent Hispanic, median years of education, and median income. For the variables percent black and percent Hispanic we compared the expected proportion from the Census with the actual proportion calculated from the completed telephone interviews for each pharmacy. We calculated the difference in number of persons between expected and actual proportions and used it to calculate a percentage of error.[9] Only seven pharmacies showed an error for percent black of 10 percent or more. These pharmacies together accounted for 14 percent of all cases. The discrepancies were always in the direction of observing a higher proportion of blacks than expected, and in all cases this involved areas with considerable population shift since the 1970 Census. The amount of error was at the same level for percent Hispanic. Only seven pharmacies, accounting for 10 percent of cases, differed by more than 10 percent from the predicted values. In all cases where the discrepancy was substantial, the observed percent Hispanic was lower than the predicted. Because non-English speaking people were excluded from the study, not all Hispanic customers were eligible. This could certainly account for the differences we found.

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[9] The percentage of error consisted of the difference in persons between expected and actual proportion black (Hispanic) divided by the number of completed cases received from the pharmacy. Pharmacies with less than eight cases were excluded from the analysis.

We used a slightly different method to compare the medians for education and income.[10] The simple correlation between medians predicted from Census data and actual medians for the 69 pharmacies (weighted by the number of cases from each pharmacy) was .61 for education and .59 for income. Of the 69 pharmacies, five (accounting for 15 percent of the cases) showed significant differences ($p < .05$) between predicted and actual values for education. Error was in both directions. For income, 17 of the pharmacies (47 percent of cases) showed significant differences ($p < .05$) between actual and predicted values. The estimated median income was lower than the predicted in most cases.

In general, estimates from 1970 Census data of characteristics of people who lived in the areas around the pharmacies were fairly good predictors of the characteristics of the pharmacy customers. This was

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[10] Data collected from participants in the study did not include a direct measure of household income. Current or most recent occupation of respondent and spouse (if present) was asked, however, and responses were coded into three digit U.S. Census occupational category codes (U.S. Bureau of the Census, 1971). To associate these codes with dollar amounts we first converted them to the equivalent 1960 U.S. Census occupation codes (U.S. Census, 1972). The 1960 categories were then classified into one of nine groups, each of which was associated with an average amount of weekly wage (in 1970 dollars). Categories and average wages were empirically derived (for male workers) by Welch and Maclennan (1976). To crudely approximate annual household income for this study, we multiplied weekly wages by 52. If the respondent was a male, his estimated annual wage was used as an estimate of household income. If the respondent was a female with spouse present, the spouse's (male) income was used as the estimate. If no spouse was present, the respondent's (female) income was used as the estimate. Clearly, the potential for misestimation is formidable. Use of crude categories, substitution of male for female wages, failure to account for retired persons, and omission of sources of income from other family members are serious threats to the accuracy of these estimates. Nevertheless, in conjunction with the other information available to assess the sample, we judged this estimate to be useful.

true despite legitimate discrepancies that could have arisen because of population change, differences between customers and residents, or differences between customers taking study drugs and all customers. Race and ethnicity were more accurately predicted than education and income. Income was least well predicted, but the estimate used for comparison in this study was subject to considerable error. For every characteristic, the range in actual values across pharmacies was wider than the predicted range from Census data. Thus, the use of Census data in sampling pharmacies produced the desired amount of diversity in the characteristics of the customers who participated in the study.

CONCLUSIONS

Both the characteristics of pharmacies and of individual subjects might affect the response to the experimental PPIs. Thus, the goal of the pharmacy selection was to sample pharmacies systematically in order to obtain diversity among the pharmacies and among the subjects they enrolled.

To do this, we classified each pharmacy in Los Angeles County by pharmacy type and by the characteristics of the residents in the surrounding area based on U.S. Census data. (Checks of the predicted characteristics of the pharmacies' customers used for this classification with the actual characteristics of the subjects we obtained from each pharmacy indicated that these data were highly predictive of the subjects we obtained.) Using the criteria we assigned, we selected a sample of pharmacies and attempted to enlist their cooperation. Refusals or dropouts were replaced with pharmacies with similar characteristics.

Although we experienced a high refusal rate among pharmacies (about 50 percent), comparisons of the participating pharmacies' characteristics with those of the pharmacy population and of the pharmacies that refused or dropped out revealed no significant differences. The high nonresponse rate did not result in a "different" sample of pharmacies along the criteria we examined.

Further, examination of the characteristics of the pharmacies and of the subjects we obtained indicates that they do represent a diverse group of Los Angeles pharmacies and prescription customers.

IV. OBTAINING CUSTOMERS WITHIN PHARMACIES

The value of a sophisticated model for selecting pharmacies to participate in the study could have easily been negated by actions in the pharmacies themselves. For example, pharmacists could have failed to ask eligible customers to participate, or those customers, when asked, could have refused to participate in the study. Either of these problems could result in a pharmacy providing too few participants or participants who did not represent a fair sampling of their eligible customers. Because the pharmacists' role in providing the sample of customers was so crucial, we designed procedures to ensure that the sampling was carried out as well as possible and to allow measurement of the accuracy of this part of the study.

Once a pharmacy had agreed to participate in the study, our field representative trained the pharmacist and any other participating staff members in how to enroll customers.[1] We visited each pharmacy at least once a week so that we could collect completed cases and provide new materials.

DETERMINING ELIGIBILITY

Pharmacy customers were eligible to participate if they were receiving a prescription for erythromycin, Dalmane, or conjugated

[1] Enrollment required five steps: (1) determining whether the customer was eligible, (2) explaining the study to the customer, (3) having the customer fill out an authorization form, (4) providing the correct PPI with the prescription, and (5) recording information about the prescription. All the necessary materials were supplied to the pharmacies in a folder.

estrogens, in tablet or capsule form. Erythromycin in liquid form was excluded because it posed special measurement problems, such as how to estimate the number of doses remaining. Conjugated estrogens in the form of a cream for topical application were also excluded, because we wished to obtain a homogeneous sample to permit accurate comparisons of usage patterns.

Eligibility was further limited to customers at least 18 years old who were picking up their own prescriptions. Erythromycin prescriptions for children were excluded to ensure that the adult sample (which could be compared across the three drugs) would be sufficiently large for analysis. The study was limited to persons picking up their own prescriptions so the pharmacist could obtain a signed authorization form allowing the release of information about the customer and the prescription to the research staff. For estrogens, eligibility was limited to women. Finally, the customer had to be able to speak English. The pharmacist was not able to determine whether the customers could read English, so that was not a requirement.

It was our original intention to limit the study to customers obtaining a first prescription for the drug, but we dropped this requirement after the pretest, because it was difficult for pharmacists to identify such customers. Many "new" prescriptions are written for people who have taken the drug previously. The pharmacist (and the patient) were not always aware when this was the case. Furthermore, first prescriptions for some drugs are a small proportion of all prescriptions that are filled. Limiting the study to first

prescriptions would have made the study prohibitively costly to carry out.[2]

All customers meeting the criteria listed above were eligible. We tried to discourage the pharmacists from applying any additional criteria of their own and strongly encouraged them to approach all eligible customers.

THE PHARMACISTS' ENROLLMENT TASK

The most important enrollment task for the pharmacists was to offer customers an opportunity to participate in a way that made them want to accept. To make this task easier for them we prepared a short brochure called "Questions and Answers About the Prescription Drug Information Study" (see Appendix A), which briefly explained the study's purpose and what would be asked of participants. The customer could read this brochure while waiting for the prescription to be filled. Customers varied considerably in how much information they wanted about the study before deciding whether to participate. The pharmacists' apparent support for the study seemed to be an important factor in the customers' decisions. Naturally, some pharmacists felt more positive about the study than others, and some found it easier to explain than others. Whenever possible, we coached pharmacists and pharmacy staff on how to describe the study to customers, and in many cases this was helpful. Some pharmacies seemed to have a more receptive clientele than others, although this is difficult to verify. For example, pharmacies in medical buildings reported having many customers who felt quite ill (for

[2] Telephone survey responses indicate that 59 percent of erythromycin subjects, 33 percent of Dalmane subjects, and 5 percent of estrogen subjects were taking the drug for the first time.

example, from very recent minor surgery), and they were unwilling to bother such customers about participating in a study.

Pharmacists were asked to tell customers that the study was about "the information people have about prescription drugs," not that it was a study of the prescription drug leaflets. This explanation was chosen for two reasons--first, both experimental and control subjects were likely to find it plausible; second, we did not wish to call undue attention to the PPI. Members of the pharmacy staffs, however, varied considerably in how they presented the study--a fact over which we had no effective control.

Each customer who agreed to participate was given an "Authorization Form" to read and sign. This form (reproduced in Appendix B) explained that the study was voluntary and the data confidential; it also outlined the procedure we would use to contact the customer for the interview. The customer supplied his or her signature and telephone number and indicated convenient times to call. The customer kept a copy of this form and the "Questions and Answers" brochure. The PPI, if any, was provided with the prescription. Pharmacists were asked to treat the PPIs as they normally would; some handed them to customers or otherwise called attention to them; others simply slipped them in the bag. However, the mere fact that customers were asked to participate in a study undoubtedly called attention to the leaflet, so the circumstances in which the leaflets were tested necessarily differ from those in which such leaflets would ordinarily be dispensed.

After the customer left the store, the pharmacist filled out a form designed for recording pertinent details of the prescription, including

the date, the number of tablets or capsules dispensed, the number of milligrams per capsule, and dosage directions. We collected this form from the pharmacies and returned it to Rand along with the signed "Authorization Form."

DETERMINANTS OF THE CUSTOMER SAMPLE

Eligible customers could fail to participate either because they were not asked or because they refused. If either of these events was systematically associated with particular types of eligible customers, biases in the sample would result. The only way to determine the extent of such biases was to obtain a description of the eligible customers who did not become part of the study. Unfortunately, we were limited in this effort in two respects: We could not obtain descriptions of customers in pharmacies that did not participate and, even in participating pharmacies, we were forced to rely on the pharmacists to collect data.[3]

Our approach to this problem was to use a brief checksheet, which we placed in each pharmacy for approximately one week. The pharmacist used this checksheet to record sex, approximate age, and type of drug for each customer obtaining one of the study drugs and to check off whether the customer was asked to participate, the outcome, and, if the customer was not asked to participate, why not. Pharmacies were paid $15 for performing this additional task. The checksheet was assigned to

[3] We did not place observers in the pharmacies. They would have had to be stationed in each pharmacy for at least a week to obtain an accurate picture of the eligible customers, which would have been prohibitively expensive and so intrusive on normal pharmacy operations that data validity would have been questionable.

each pharmacy for a randomly selected week during the fifth through eighth months of the study.[4]

Sixty of the most cooperative pharmacies completed checksheets. Together, these pharmacies enrolled 93 percent of all completed cases. Of the pharmacies that completed the checksheets, 90 percent reported that they had achieved total coverage: all pharmacists had filled it out for all times of day. The checksheet was filled in for a mean of 6.5 days in each pharmacy, so can be taken to represent about one week of data. Together, the checksheets described 643 pharmacy customers who presented prescriptions for one of the study drugs.

Our analysis revealed that pharmacists enrolled more than the usual number of participants during the weeks that they filled out the checksheet--a mean of 3.2 cases received per pharmacy each week versus 1.9 in other weeks. (This difference in the means is significant at $p < .005$.) Thus, the checksheet apparently served as a reminder for the pharmacists, although it was hardly one they would have willingly accepted for an extended period. We regard the checksheet weeks as "ideal" weeks--ones in which pharmacists' cooperation was unusually high. During these weeks, pharmacists asked 297 people (46 percent of all customers picking up prescriptions for study drugs) to participate and 166 agreed (56 percent of those asked). Fifty-four percent were not asked.

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[4] It might have been possible to check on the accuracy of these checksheets through the pharmacies' prescription records. We chose not to do this during the data collection period to avoid placing further burdens on the pharmacies (and possibly losing their cooperation). We were unable to undertake it later for cost reasons. The checksheets, then, might over- or underestimate the actual numbers of eligible customers.

Table 3 shows the reasons the pharmacists provided for not asking customers to participate. The main reasons were that the prescription was to be delivered to the customer, that someone else was picking it up, or that the customer was too young to participate. Each of these reasons involved legitimate application of the study's criteria for

Table 3

PHARMACISTS' REASONS FOR NOT ASKING CUSTOMERS TO PARTICIPATE IN THE STUDY[a]

Reason	Percent of All Customers Not Asked
Related to Eligibility	
Prescription picked up by someone else	30
Prescription delivered	23
Customer too young	17
Customer did not speak English	6
Customer had already participated	2
Customer had no telephone	<1
Not Related to Eligibility	
Pharmacist too busy	12
Customer exceptionally difficult to deal with	5
Medi-Cal customer	1
Pharmacist ran out of study materials	1
Pharmacist forgot to ask	1
Customer too old	1
Customer in a hurry	<1
TOTAL	100

[a]Based on data provided by 60 pharmacists on 346 customers filling prescriptions for one of three study drugs during a randomly selected week.

eligibility. Along with certain less frequently reported reasons involving other criteria, exclusion on the basis of eligibility accounted for 79 percent of the customers who were not asked. The rest of the cases (21 percent) involved customers who should not have been excluded based on the eligibility criteria. These were cases where the pharmacist was too busy to talk with the customer or felt that there was some reason, other than the eligibility criteria, why the customer should not participate (too old, Medi-Cal patient, etc.). The reasons for not asking varied slightly by drug: "Customer was too young" was cited frequently for erythromycin, "non-English speaking customer" was cited frequently for Dalmane, and "delivery" was reported frequently for estrogen and, to a lesser extent, for Dalmane.

Analysis of the checksheets revealed that the pharmacists were not equally likely to ask eligible customers to participate across the drugs. Whereas only about 11 percent of all the eligible customers during the checksheet weeks were not asked to participate, the figure was higher for Dalmane (14 percent) than for erythromycin (9 percent) or estrogen (10 percent). These differences are significant at $p < .05$. Pharmacies did enroll more customers during the checksheet weeks than during other study weeks, so the above figures are almost certainly an understatement of the percentage of customers that pharmacists "missed" during the course of the study. If we assume that the number of eligible customers was approximately the same during checksheet weeks and other weeks, and further assume that the percentage of customers who agreed to participate (from among those asked) was also the same, then

we estimate that in other weeks pharmacists approached only about 50 percent of all eligible customers.

Although the question of how many of the eligible customers were approached is important (especially in determining the cost of conducting the study), it is secondary to the more important question of whether pharmacists' selection behavior introduced any sample bias. If pharmacists' decisions about approaching customers were determined by factors unrelated to the characteristics of the customers themselves, then even a very low solicitation rate would yield a fairly representative sample. If pharmacists made their decisions partly or wholly on the basis of customer characteristics, however (e.g., by screening out the elderly), then some sample bias would result.

To address the question of whether customers who were not asked to participate differed from those who were, we used the data from the checksheets to compare the two groups of customers (eligibles who were and were not asked to participate) with respect to the two demographic categories for which we had information--sex and age. We examined the data for the three drugs combined, and separately for each drug. Using a significance level of $p < .10$, we found no significant differences by sex or age in the percentage of eligible customers who were asked to participate.

Naturally, any differences in the customers' willingness to participate when asked to do so by the pharmacists also introduce bias. Using the checksheet data, we made a comparison according to age and sex of customers who agreed to participate and those who refused. We found that females were more likely to agree to participate than males; 66 percent of the female erythromycin customers agreed, but only 50 percent

of the males (difference significant at $p < .10$). A similar trend appeared for Dalmane customers; 57 percent of the females agreed but only 50 percent of the males (although in this case the difference is not statistically significant). We found no significant difference in willingness to participate by age when we examined the data for all drugs combined or separately for each drug.

Because pharmacists were so diligent in recruiting participants during the weeks they filled out checksheets, the cases enrolled during those weeks represent the sample of cases we would have liked to obtain throughout the study, but not necessarily the sample we actually did obtain. For obvious reasons, the checksheet data do not permit us to determine how customers who were solicited during checksheet weeks compare with those who were solicited in other weeks. We can, however, make an analogous comparison among those who completed telephone interviews. To assess possible biases that might have resulted from pharmacists' lower solicitation rates during other weeks, we identified the customers who enrolled in the study during weeks when checksheets were in place and compared them with the other customers who completed telephone surveys.

As shown in Table 4, we compared the two groups of customers along five dimensions--sex, age, education, race, and the setting in which they usually saw their doctor (clinic, private office, etc.). Using a significance level of $p < .10$, we found only two significant differences between the cases collected during the checksheet and other weeks. For the Dalmane sample, more older people became participants during the checksheet weeks (a mean age of 61 rather than 54 years--$p < .01$.

Table 4

SIGNIFICANCE LEVELS FOR COMPARISONS AMONG SUBJECTS RECRUITED DURING CHECKSHEET AND OTHER WEEKS

	Erythromycin	Dalmane	Estrogen
Age[a]	.30	.01	.55
Sex[b]	.41	.87	(c)
Race[d]	.82	.72	.68
Education[a]	.41	.95	.49
Treatment setting[d]	.21	.96	.01

[a]Based on t-test on breakdowns.

[b]Based on Chi-square test for contingency table (df=1).

[c]Not applicable.

[d]Based on Chi-square test for contingency table (df=5).

For the estrogen sample, more subjects who obtained prescriptions in clinic or hospital settings were enrolled during the checksheet weeks (significant at $p < .01$). No other significant differences appeared, either for the drugs examined separately or for all the participants considered together. Thus, with those two exceptions, the pharmacists did not bias the sample along these dimensions during weeks when they provided fewer participants; they simply asked a smaller, but generally representative, proportion of their eligible customers to participate.

CONCLUSIONS

Conducting this experiment in the most natural circumstances possible meant that the pharmacists were responsible for identifying

and enrolling subjects. We believe that they asked about half of the eligible customers to participate. Erythromycin and estrogen customers were most likely to be asked but, based on the pharmacists' reports, we found no significant age or sex differences between the customers who were and were not asked to participate.

About 56 percent of the customers who were asked agreed to participate. Females were significantly more likely to agree, but there were no age differences in acceptance rates.

To obtain these data, we placed a checksheet in each pharmacy for a period of about a week. This resulted in significantly higher rates of enrollment during those weeks, creating a subsample of subjects enrolled during periods when nonsolicitation effects were minimal. We compared this subsample with the rest of the sample along the dimensions of age, sex, race, educational attainment, and medical treatment setting. Using a conservative criterion of $p < .10$, we found two significant differences out of 14 comparisons. Older Dalmane subjects and estrogen subjects drawn from clinic, hospital, and HMO settings appear to have been somewhat underrepresented because of the combination of differential rates of solicitation and acceptance.

Although the solicitation and acceptance rates were fairly low, this caused more of a problem in its effect on the cost of conducting the study (it meant a longer period of time in the field) than in creating sample bias. Overall, we believe the pharmacies were successful, if slow, in obtaining a fair representation of their customers as study participants.

V. ASSIGNMENT OF PPIS TO CUSTOMERS

In addition to recruiting subjects, pharmacists were also responsible for assigning the correct PPI to participants. Because pharmacists typically work in a very small space and are quite harried, we tried to make the assignment procedure as simple for them as possible. Accordingly, we devised a system whereby the PPIs and other experimental materials were randomly ordered for the pharmacists before these materials were placed in the pharmacies. For each prospective customer, we assembled a set of materials that included a "Questions and Answers" brochure, an Authorization Form, a PPI (if applicable), and a Prescription Information Sheet (see Appendix C); these were clipped together in a set. A code number for the experimental condition (type of PPI) was prerecorded on the Prescription Information Sheet. If no PPI was included (the case was to be assigned to the control group) a note to the pharmacist was clipped to the packet in lieu of the PPI. Each pharmacy received a one week supply of materials arranged in separate folders for each drug. These folders, along with extra materials, were placed inside a larger folder, on the front of which were instructions for enrolling customers (see Appendix D). PPIs within each study were numbered one, two, three, and four; zero was used to designate the control condition. Each week one of these numbers was randomly selected to be the initial PPI number, and a set of materials containing that PPI number was placed first in the folders for each drug. The rest of the PPIs were placed in numerical order behind the randomly determined PPI number. (For example, if the week's initial

sort number was three, the PPIs in each folder that week would be in the order: 3,4,0,1,2,3,4.) The pharmacist's task was to select the first available set from the folder for each customer that agreed to participate. If the customer refused to participate after the set of materials was removed, the pharmacist was supposed to replace it in the front of the folder. Completed forms were placed in another folder for pickup.

Pharmacies did not always have a full complement of all PPIs at one time. Which ones they received was based on the overall assignment of PPIs to all the pharmacies, as well as the assignment within individual pharmacies. Each week we generated a report that showed which PPIs were assigned and waiting to be given out in the pharmacies and which PPIs had been given to enrolled customers. Based on tallies from these reports we decided which PPIs should be assigned to maintain proper balance in PPI assignment across all the pharmacies. We also attempted, insofar as possible, to balance the PPIs assigned within each pharmacy. Because cases were systematically ordered after a random start number within each pharmacy, a PPI assigned one week might not be given out for some time, especially in pharmacies where the volume of enrollments was low. This meant that our control over which PPIs were assigned in a given week was imperfect and delayed in its effect.

We considered placing the PPIs in envelopes so that the pharmacist would not know which PPI was being given out, but decided against it. If the PPIs were provided to customers in sealed envelopes, a certain amount of naturalism would be lost, because such a delivery method is not contemplated under regulatory policy. Alternatively, if the PPIs were

to be removed from the envelopes just before the delivery to customers, the advantage of blind assignment would be lost, and removal of the PPIs would require an extra procedural step. Moreover, pretest results suggested that PPIs would not be reliably removed in the pharmacies. For these reasons, we elected to follow a simpler and more natural procedure; we arranged each packet so that the PPI was in the middle of each set of forms and relied on the pharmacists simply to hand out the first set in the folder without looking at it.

ASSESSMENT OF PHARMACIST'S ROLE IN THE EXPERIMENTAL MANIPULATION

At least three kinds of errors could have occurred in the pharmacies. The pharmacists could have selected certain PPIs to give out while withholding others, they could have assigned PPIs differentially to certain classes of customers, or they could have mixed up materials from different packets so that we could no longer tell which PPI they gave out to an individual customer. We checked for all of these errors.

Selection of PPIs To Give to Participants

A Rand staff member who visited each pharmacy weekly took an inventory of the content of the packets. For each different version of the PPI she counted how many of each PPI the pharmacy had and how many had been given out. She then recorded how many new PPIs she added. The prerecorded random sort number was used to re-sort the sets of PPIs within each folder. These weekly inventory records later provided the basis for determining how well the pharmacists carried out the random

assignments. Analysis of these records revealed that pharmacists delivered the PPIs in the proper order to 78 percent of the participants. The rest of the PPIs (22 percent) were assigned out of order.

This error rate is sufficiently large to justify concern about the possibility of some systematic bias in the experimental assignment. Accordingly, it is important to examine this error more closely, to determine whether it resulted from factors that threatened the integrity of the experiment.

The sources of error that concern us are those that result from substitution of systematic pharmacist control for experimental control over assignment. Not all out-of-order assignments fall into this category. For example, suppose that the pharmacist were to remove a set of materials from the folder and then replace it after a customer refused to participate. If the pharmacist were to replace the unused set in the wrong place--e.g., at the back of the packet instead of the front--all subsequent assignments for the week would be "out of order." Such an error would, however, be unsystematic, and would not introduce any bias into the assignment procedure. If, however, the pharmacist made a practice of removing a packet, examining the PPI, and deciding whether or not to give it to a particular customer because it was or was not one of the "better" PPIs, bias might result. Fortunately, it is possible to examine the weekly inventory records for evidence of the kind of assignment error we are most concerned about.

If pharmacists systematically favored some PPIs over others in their assignments, these biases would result in differential error rates

for individual PPIs. Accordingly, we performed a contingency analysis of the data from our inventory records, examining the number of correct and incorrect assignments for each PPI and the no PPI control for each study. The results are summarized in Table 5. As the table shows, the percentage of correct assignments does vary significantly from condition to condition ($\chi^2 = 79.5$, df = 36, $p < .005$). For six of the nine study/drug comparisons, the pharmacists correctly gave out PPI cases more frequently than no PPI cases ($p < .10$). This occurred most often for estrogen and Dalmane cases, but occurred for all three drugs and occurred consistently in Study 2. Erythromycin showed significant variation among PPIs for Study 1 ($p < .05$), but this was the only instance of differentially correct assignments among the PPIs. Thus, the pharmacists seem to have preferred assigning <u>any</u> PPI to <u>no</u> PPI, but there was only a slight indication of any selection from among the PPIs.

However, this is a matter of serious concern only if pharmacists decided whether to give the PPI to individual customers on the basis of customer characteristics. For example, the pharmacists might not consistently withhold a particular PPI but might avoid giving it to certain customers. To check this possibility, we compared participant characteristics along the dimensions of age, sex, race, education, and medical care setting according to which of the PPI variations (including no PPI) they received, as shown in Table 6. With an alpha level set at .10, we found no significant differences by type of PPI for any characteristic. So far as we could determine, departures from randomness were due to nonsystematic errors on the part of the pharmacists and should not affect experimental results.

Table 5

PPI ASSIGNMENTS BY DRUG AND STUDY

Erythromycin	Percent Correctly Assigned	(Total cases)	Dalmane	Percent Correctly Assigned	(Total cases)	Estrogen	Percent Correctly Assigned	(Total cases)
Study 1[d]			Study 1[c]			Study 1[b]		
No PPI control	85	(33)	No PPI control	53	(30)	No PPI control	56	(39)
PPI #1	72	(78)	PPI #1	74	(45)	PPI #1	78	(50)
" #2	77	(74)	" #2	84	(45)	" #2	69	(45)
" #3	92	(61)	" #3	74	(46)	" #3	77	(53)
" #4	79	(71)	" #4	83	(41)	" #4	78	(51)
Study 2[c]			Study 2[c]			Study 2[b]		
No PPI control	62	(29)	No PPI control	42	(26)	No PPI control	57	(21)
PPI #1	87	(71)	PPI #1	73	(48)	PPI #1	82	(57)
" #2	87	(55)	" #2	80	(45)	" #2	78	(49)
" #3	87	(53)	" #3	85	(34)	" #3	66	(41)
" #4	85	(59)	" #4	90	(30)	" #4	80	(35)
Study 3			Study 3			Study 3[a]		
No PPI control	79	(62)	No PPI control	69	(13)	No PPI control	65	(55)
PPI #1	85	(120)	PPI #1	65	(20)	PPI #1	84	(49)
" #2	86	(105)	" #2	60	(20)	" #2	79	(52)
" #3	89	(99)	" #3	60	(20)	" #3	69	(42)
" #4	90	(105)	" #4	70	(23)	" #4	60	(30)

[a] Chi-square test for PPI vs. no PPI (df=1) significant at alpha level of <.10.

[b] Chi-square test for PPI vs. no PPI (df=1) significant at alpha level of <.05.

[c] Chi-square test for PPI vs. no PPI (df=1) significant at alpha level of <.01.

[d] Chi-square test for within PPIs (df=3) significant at alpha level of <.05.

NOTE: Totals sum to 2,030 cases, which includes all cases ever enrolled.

Table 6

SIGNIFICANCE LEVELS FOR COMPARISONS AMONG SUBJECTS BY TYPE OF PPI RECEIVED[a]

aa

	Erythromycin	Dalmane	Estrogen
Age[b]	.80(.99)	.99(.85)	.71(.25)
Sex[c]	.12(.70)	.18(.30)	(d)
Race[e]	.46(.42)	.50(.48)	.50(.73)
Education[b]	.40(.22)	.33(.99)	.39(.99)
Treatment setting[f]	.85(.41)	.68(.30)	.42(.28)

[a]Significance points in parentheses are for comparisons between those who received any PPI versus those who received none.

[b]Based on F-statistic.

[c]Based on Chi-square with df=12 (df=1).

[d]Not applicable.

[e]Based on comparison of white with all other races, df=12 (df=1).

[f]Based on comparison of private office with all other settings, df=12 (df=1).

Validity of Study Assignment Records

Our ability to establish causal links between the experimental manipulations and the results requires that we know which participant received which experimental PPI. The sets of materials assembled for each participant were clipped together with paperclips so that the pharmacists could separate them easily as they used them. Although we checked the materials weekly, materials may occasionally have become separated in the pharmacies and then reassembled incorrectly. This

could result in a participant's receiving a different PPI from the one we thought he had received, which would obviously cause problems in assessing the effects of PPI variations.

To check this we added questions to our routine validation of the telephone interview (described more completely in Section VI), which was conducted with 284 participants.[1] The time between telephone interview and validation ranged from a few days to a few weeks. We asked each participant whether he had received a PPI and, if so, whether he still had it and could read the number to us over the telephone. About a third of those who had received a PPI could find it. All of the participants who gave us a number (74 cases) gave the correct number. Thus, our records concerning which PPI was given out to participants who received a PPI seem to have been quite accurate.

However, we did encounter a problem with the no PPI cases. For the erythromycin and Dalmane cases, slightly over half of the no PPI participants claimed during the telephone interview to have received a PPI. Those who were validated repeated this claim (test-retest reliability of .93). Although this is somewhat a matter of the participants trying to be "helpful" to the interviewer,[2] in fact, out

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[1] We did not place these questions in the actual telephone survey because asking respondents to find their PPI and bring it to the telephone would have imposed an additional burden on them, one that we were not anxious to impose so soon after asking them to find and count their pills.

[2] Respondents who said they had received a PPI were then asked a number of specific questions about it. Comparison of the no PPI cases who claimed they received a PPI with the actual PPI cases revealed a much higher proportion of "don't know" responses and other kinds of missing data among the no PPI cases. Although these respondents indicated that they had received a PPI, they had considerable difficulty answering questions about it--suggesting that many of them had not, in fact, received one.

of nine erythromycin no PPI cases, three were able to provide a valid PPI number during validation. This did not occur for Dalmane or estrogen. We speculate that pharmacists may occasionally have given out one of their sample PPIs to a no PPI case, perhaps because they thought the PPI had become detached from the rest of the materials. Although we do not believe that this occurred frequently enough to pose a serious problem, the error it introduced obviously reduces the sensitivity of our analysis of effects of receiving versus not receiving a PPI.[3]

CONCLUSIONS

The pharmacies were responsible for carrying out random assignment of PPIs to subjects as part of the enrollment process. Because we knew how busy the pharmacies were, we designed this procedure to be as simple as possible; the pharmacist had only to give out the first packet of materials in the folders. Nevertheless, errors occurred. Because improper assignment of one packet caused all subsequent packets that week to be assigned out of order, we can only place an upper bound estimate on the error rate of about 22 percent. The pharmacists underassigned cases that received no PPI but did not discriminate among the PPIs. We speculate that on pulling out a packet with no PPI they may have assumed that we had made an error and assigned the next case, although we tried to forestall that possibility by attaching a note to each no PPI case. They may also have occasionally given out a spare PPI with some of the no PPI cases.

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[3] If some of the no PPI cases had actually received PPIs, the observed effects of receiving a PPI would be reduced. Thus, our results would tend to underestimate the effects of receiving a PPI.

Although regrettable, these errors in assignment do not threaten the integrity of the experiment if they do not represent systematic attempts to assign particular PPIs or no PPI cases to particular classes of subjects, and this appears to be the case. Comparing subject characteristics along the dimensions of age, sex, race, educational attainment, and treatment setting for all PPIs (including no PPI) and specifically for PPI versus no PPI, we found no significant differences (using a conservative significance level of $p < .10$ across the 15 comparisons).

Although the pharmacists appeared to have some difficulty carrying out the random assignment procedure, their errors did not result in systematic bias along any of the dimensions we examined and might lead to slight underestimates, not overestimates, of PPI effects.

VI. OBTAINING DATA FROM PHARMACY CUSTOMERS

Participants were interviewed by telephone shortly after they filled their prescription. The interviews took an average of 45 minutes each and covered the participants' experience with and knowledge about the drug and their reactions to the PPI. It also included a test of general medical knowledge and a group of standard demographic items.[1] At the end of the telephone interview, the interviewer asked whether the respondent would be willing to fill out a mail survey. If the respondent agreed, the survey was sent to the respondent along with a check for $2.50 as payment for participation. Finally, a portion of each interviewer's work was selected for validation. We recontacted the respondent by telephone to confirm that the interview had taken place and to ask for some additional information.

CONTACT PROCEDURES FOR THE TELEPHONE SURVEY

Members of the Rand staff visited each pharmacy weekly to collect materials about any new participants that the pharmacist had enrolled in the study. This information was logged at Rand and turned over to the telephone interviewing staff. The first call was made at a day and time specified by the respondent. Erythromycin cases were called as soon as possible because the course of treatment is usually short (about five to ten days) and we wanted to interview participants while they were taking the drug. Dalmane and estrogen cases were held for a minimum of ten days

[1] The questionnaires are reproduced in Appendixes B through D of Kanouse et al. (1981a).

after the date the prescription was filled so that the participants would have time to gain experience with the drug before the interview.

We attempted to complete the interview on the first call whenever possible. If we failed to reach the respondent, we made a minimum of six calls (including a weekday, evening during the week, and weekend) before retiring the case. Once we reached the respondent, we made considerable effort (up to 16 calls) to complete the interview, although 75 percent of the cases reached a final status after three calls and 99 percent were final after eight calls.[2]

Table 7 shows the disposition of cases from the telephone interviewing. Overall, 82 percent of the cases received from the pharmacists resulted in completed interviews. If we disregard cases that were ineligible because of incomplete or improperly prepared enrollment materials (7 percent of all cases),[3] the interview response rate was 87 percent and the combined refusal and breakoff rate was 6 percent.[4] The remaining 8 percent of the cases are counted as contact failures--eligible cases where we failed to reach the respondent for an interview. The response rate varied slightly across drugs--89 percent for estrogen, 88 percent for erythromycin, and 82 percent for Dalmane.

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[2] The number of calls required to reach final status in this study compares favorably with similar studies we have conducted. But we do not believe that making the first call at the time specified by the participant resulted in substantially increased efficiency, although pharmacists and participants may have perceived the survey to be less burdensome because of that feature.

[3] For the most part, these errors were detected when cases were checked in at Rand, before the telephone interview. A few were detected during the first telephone contact with the respondent.

[4] Response and refusal rates were calculated according to the formulas recommended in Bailar and Lanphier (1978).

Table 7

OUTCOME OF ATTEMPTS TO COMPLETE THE TELEPHONE INTERVIEW

Final Status of Interview	Number of Cases	Percent of All Cases[a]	Percent of Eligible Cases[a]
Participant enrollment problem			
Can't locate participant, wrong telephone number	68	3	
Authorization form not signed by participant	43	2	
Error in information about type of drug or PPI	23	1	
Participant was previously interviewed	16	1	
Contact failure			
Retired after maximum calls	105	5	5
Participant not available during field period	37	2	2
Participant could not remember prescription	12	1	1
Survey outcome			
Complete interview	1820	81	87
Refusal	75	3	4
Breakoff/Incomplete	31	1	2
TOTAL	2230	100	100

[a]Percentages may not sum to 100 because of rounding.

All reasons for failure to complete the interview were slightly more pronounced among Dalmane cases.

CONTACT PROCEDURES FOR THE MAIL SURVEY

Only eight respondents who completed the telephone interview refused to accept the mail survey along with their payment for participation. (One person refused payment.) The rest received their

payment (in the form of a check) and the mail survey within about a week after the interview.[5] A reminder postcard was sent to all respondents one week after the initial mailing and a letter was sent ten days after the first mailing if the survey had not been received. A final letter, including another copy of the survey, was sent out about 20 days after the first mailing. Only a few of the mailings were returned by the post office as undeliverable.

These procedures yielded an overall completion rate of 82 percent. This rate was highest for estrogen participants--88 percent. Completion rates for erythromycin and Dalmane were each 79 percent. Older people were more likely to complete the survey; 38 percent of completions were over age 56 compared with 21 percent of noncompletions (Chi square is significant at $p < .0001$). Eighty percent of the completions were female, compared with 72 percent of the noncompletions (significant at $p < .005$); and 83 percent of the completions were white, compared with 63 percent of the noncompletions (significant at $p < .0001$). No significant relationship was found between education and completion.

VALIDATION OF THE TELEPHONE INTERVIEWS

As mentioned previously, we conducted short validation interviews with 284 participants who had completed the telephone interview (16 percent of the completions). Because the validation was intended as a check on field procedures (rather than as a means of generating item reliability estimates), we selected a portion of each interviewer's work

[5] Mail survey response rates seemed to be sensitive to the time elapsed between the interview and receiving the survey. If the mail survey was delayed for any reason, response rates declined.

for validation.[6] Eighty-seven percent of the participants selected for validation completed a validation interview; only four refused to participate (the rest could not be reached after three calls). The validator verified the interview date and asked how long the interview took. The respondent was also asked about receiving the PPI, as described in Section IV. We encountered no problems in the cases we validated.

CONCLUSIONS

Survey procedures yielded acceptable levels of completion for the telephone and mail surveys. Results of the validation revealed no problems with interviewer performance. Comparisons of participants who completed the mail survey with those who did not complete it revealed some significant differences, which should be considered when data from this source are analyzed.

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[6] We also monitored interviewers on a regular basis by listening to actual interviews.

Appendix A

QUESTIONS AND ANSWERS BROCHURE

ANSWERS TO SOME QUESTIONS ABOUT THE PRESCRIPTION DRUG INFORMATION STUDY

Rand
SANTA MONICA, CA. 90406

WHAT IS THE PRESCRIPTION DRUG INFORMATION STUDY?

The U.S. Government must decide whether rules are needed and what kind of rules should be in effect for prescription drugs. To decide these things sensibly, the government needs information about how drugs are actually used by the public. That is why the government asked for this research and that is why we are asking for your help.

WHO IS DOING THE STUDY?

The U.S. Department of Health, Education and Welfare asked The Rand Corporation to carry out this study. Rand is a private, non-profit research organization established in 1948 to do research in the public interest. Rand is located in Santa Monica, CA.

WHY IS MY PHARMACIST INVOLVED?

Rand chose a group of pharmacies in the Los Angeles area and asked for their help. These pharmacies, in turn, agreed to ask their customers to be part of the study. You do not have to participate and the service you get from your pharmacy won't be affected by your decision either way.

WHAT IS THE AUTHORIZATION FORM?

The authorization form allows the pharmacy to give Rand information about your prescription and your name, address, and telephone number. If you think you would like to be part of the study, sign the form your pharmacist will give you.

WHAT HAPPENS NEXT?

In a week or two someone from Rand will contact you by telephone. They will answer any questions you have about the study and ask to interview you. For most people it will all be done on the telephone. In a few cases, they will ask to interview you in your home at a time that is convenient for you. You can change your mind about the study and refuse to participate at any time. It is completely voluntary.

WHAT IS THE INTERVIEW LIKE?

It will take about half an hour, and the questions are easy to answer. They are about the medicine you received, your experience with the symptoms it was prescribed to help, and a few questions about yourself. You can stop at any time and you can refuse to answer any question. Since it will take some of your time, you will be paid $2.50 for your cooperation in the interview.

WILL ANYONE KNOW I'M PART OF THE STUDY?

Not unless you tell them. We will speak only with you, personally, about the study, and we will not mention the name of the study to anyone else, even in your household.

WHAT HAPPENS TO THE INFORMATION I PROVIDE?

The answers you provide will be combined with the answers of all the other people participating in the study. They will be reported as totals, averages and statistics. All information which would permit identification of you or your household will be regarded as strictly confidential, will be used only for the purposes of the study, and will not be disclosed or released for any other purpose without your prior consent, except as required by law.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Call The Rand Corporation at (213) 393-0411
Ask for Miss Sandra Berry, Ext. 689.

THANK YOU FOR TAKING THE TIME TO LEARN ABOUT THIS IMPORTANT RESEARCH. We hope you will join your pharmacist and Rand as a participant in the study. Please keep this booklet until the study is over in case you have questions.

Appendix B

AUTHORIZATION FORM FOR PARTICIPANTS

Rand
SANTA MONICA, CA. 90406

PRESCRIPTION DRUG INFORMATION STUDY

Authorization Form for Participants

I. Prescription Drug Information Study

The Prescription Drug Information Study is being carried out by The Rand Corporation, Santa Monica, CA in cooperation with pharmacists in the Los Angeles area. It is sponsored by the U.S. Department of Health, Education, and Welfare. Its purpose is to learn more about how to communicate drug information to consumers.

II. Information Provided by My Pharmacy

I agree to allow my pharmacy to provide The Rand Corporation with my name, telephone number, and information about the prescription I received today. No additional information will be provided to Rand by my pharmacy.

III. Information I Provide

I understand that an employee of The Rand Corporation will contact me to administer an interview. This interview will take about half an hour and I will be paid $ 2.50 for participating. It will include questions about the medicine I am taking, my experience with the symptoms it was prescribed to help, and a few questions about myself. Rand will answer any questions I have about the study.

IV. Voluntary Nature of Prescription Drug Information Study

I understand that I do not have to participate in this study. My decision whether or not to take part will not affect any services I receive from this pharmacy. I also understand that I can decide not to participate at any point and that I am free to not answer any question in the interview.

V. Confidentiality of Information

I understand that the answers I provide will be combined with those of other participants in reporting study findings. In addition, all information which would permit identification of me or my household will be regarded as strictly confidential, will be used only for the purposes of this study and will not be disclosed or released for any other purpose without my prior consent, except as required by law.

PLEASE PRINT YOUR NAME:

MISS MR.
MRS. MS. _____

FIRST NAME LAST NAME

_____ _____

YOUR SIGNATURE DATE

Telephone Number Where We Can Contact You: _____

Is this your home number? ☐ YES ☐ NO

When is the most convenient time to call you?

DAY(s) _____ Time: _____ AM PM

DAY(s) _____ Time: _____ AM PM

Appendix C

INFORMATION PROVIDED BY PHARMACISTS

Rand
1700 MAIN STREET
SANTA MONICA, CA.90406

PRESCRIPTION DRUG INFORMATION STUDY
PARTICIPANT INFORMATION SHEET
ERYTHROMYCIN

1-4/

5/1

(OFFICE USE)

RAND CASE # [ ][ ][ ] - [ ] - [ ] - [ ][ ][ ][ ] 16-14/
Pharmacy Study Drug ID

PPI # GIVEN TO PATIENT: [ ] - [ ] - [ ] 15-17/

AFFIX COPY OF LABEL IF AVAILABLE ———

PLEASE FILL IN BELOW ANY INFORMATION NOT CONTAINED ON LABEL.

YOUR Rx # _____ 18-25/

DATE DISPENSED _____ / _____ / _____ 26-31/
MONTH DAY YEAR

COST OF PRESCRIPTION TO CUSTOMER: $_____ . ____ 32-36/

(OFFICE USE)

BRAND NAME DISPENSED _____ [ ][ ] 37-38/

MG PER TABLET _____ 39-40/

TABLETS DISPENSED _____ 41-42/

DIRECTIONS FOR TAKING DRUG:

TAKE: ONE [ ] 43/ TWO [ ] 44/ (OR)

FILL IN:

TIMES A DAY _____ 47-48/

(OR) EVERY X HOURS (FILL IN HOURS)_____ 49-50/

(OR) "AS DIRECTED" [ ] 51/

OTHER # OF PILLS: _____ 45-46/

NAME OF PATIENT: _____ _____
FIRST NAME INITIAL

_____
LAST NAME

Rand
1700 MAIN STREET
SANTA MONICA, CA.90406

PRESCRIPTION DRUG INFORMATION STUDY
PARTICIPANT INFORMATION SHEET
DALMANE

1-4/ 5/1

(OFFICE USE)

RAND CASE # [ ][ ][ ] - [ ] - [ ] - [ ][ ][ ][ ] 6-14/
Pharmacy Study Drug ID

PPI # GIVEN TO PATIENT: [ ] - [ ] - [ ] 15-17/

AFFIX COPY OF LABEL IF AVAILABLE →

PLEASE FILL IN BELOW ANY INFORMATION NOT CONTAINED ON LABEL.

YOUR Rx # _____ 18-25/

DATE DISPENSED _____ / _____ / _____ 26-31/
MONTH DAY YEAR

COST OF PRESCRIPTION TO CUSTOMER: $_____ . ____ 32-36/

MG PER TABLET: 15 MG ☐ 37/
30 MG ☐ 38/
OR _____ MG 39-40/

TABLETS DISPENSED: _____ 41-42/

DIRECTIONS FOR TAKING DRUG:

TAKE: ONE ☐ 43/ PER NIGHT ☐ 48/
TWO ☐ 44/ "AS NEEDED" ☐ 49/
(OR) ONE OR TWO ☐ 45/ OTHER DIRECTIONS: _____

OTHER # OF PILLS: ____ ____ 46-47/

(OFFICE USE) [ ][ ] 50-51/

NAME OF PATIENT: _____ _____
FIRST NAME INITIAL

_____
LAST NAME

Rand
1700 MAIN STREET
SANTA MONICA, CA.90406

1-4/

PRESCRIPTION DRUG INFORMATION STUDY
PARTICIPANT INFORMATION SHEET
ESTROGEN

5/1

(OFFICE USE)

RAND CASE # [ ][ ][ ] - [ ] - [ ] - [ ][ ][ ][ ] 6-14/
Pharmacy Study Drug ID

PPI # GIVEN TO PATIENT: [ ] - [ ] - [ ] 15-17/

AFFIX COPY OF LABEL IF AVAILABLE →

PLEASE FILL IN BELOW ANY INFORMATION NOT CONTAINED ON LABEL.

YOUR Rx # _____ 18-25/

DATE DISPENSED _____ 26-31/
MONTH DAY YEAR

COST OF PRESCRIPTION TO CUSTOMER: $_____ . ____ 32-36/

BRAND NAME DISPENSED _____ (OFFICE USE) [ ][ ] 37-38/

MG PER TABLET _____ 39-40/

TABLETS DISPENSED _____ 41-42/

DIRECTIONS FOR TAKING DRUG:

TAKE: ONE [ ] 43/ "AS DIRECTED" [ ] 47/

(OR) TWO [ ] 44/ EVERY WEEK [ ] 48/

OTHER # OF PILLS: ____ ____ 45-46/ EVERY OTHER DAY [ ] 49/

(OR) OTHER DIRECTIONS: _____

(OFFICE USE)

_____ [ ][ ] 50-51/

NAME OF PATIENT: _____ _____
FIRST NAME INITIAL

_____
LAST NAME

Appendix D

ENROLLMENT INSTRUCTIONS FOR PHARMACISTS

PRESCRIPTION DRUG
INFORMATION STUDY

HOW TO SIGN UP
A PARTICIPANT
IN THE STUDY

1. Try to ask EACH eligible customer to be part of the study. We need all kinds of people.

2. ELIGIBLE means:
   - Age 18 or over.
   - Picking up own prescription.
   - Drugs are erythromycin, Dalmane, and conjugated estrogen.
   - All drugs in pill or capsule form (no creams or liquids).
   - For estrogen, only females are eligible.
   - Must speak English (don't worry about reading).

3. Please tell each eligible customer (a suggestion):

   - There's a study going on about the information people have about prescription drugs, and it includes people who are getting (NAME OF DRUG).
   - It's being done by The Rand Corporation in Santa Monica for the U.S. government and we're working with Rand.
   - Would you be willing to be part of the study? If you are, someone from Rand will call you to do an interview with you over the phone and they'll pay you $2.50.
   - This leaflet (Q and A) is for you and it explains more about the study.

4. When the customer says YES:

   - Pick out the first set of materials from the folder.
   - Ask the customer to fill out and sign the Authorization Form.
   - Give the customer
     - the PPI (unless its a "NO PPI" case)
     - the yellow copy of the Authorization Form
     - the Q and A leaflet
   - Fill in the "Participant Information Sheet" or put your label on it. Put it with the signed Authorization Form in the "COMPLETE" folder. That's it!

5. IF YOU HAVE ANY PROBLEM CALL SANDY BERRY OR DAVID KANOUSE AT 393-0411.

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